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10/532,832	01/04/2006	Tetsuo Miyayama	270262US0PCT	8791	
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ALEXANDRIA, VA 22314		ART UNIT	PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 10/532 832 MIYAYAMA, TETSUO Office Action Summary Examiner Art Unit ABIGAIL FISHER 1616 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 20 March 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-6 and 8-11 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-6 and 8-11 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTC/G5/08)
Paper No(s)/Mail Date ______

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Request for Continued Examination and Amendments/Remarks filed on February 29 2008 and Supplemental Response, Amendments/Remarks, and Declaration under 37 C.F.R. 1.132 filed on March 20 2008 is acknowledged. Claim 7 were/stand cancelled. Claim 6 was amended. Claims 1-6 and 8-11 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Applicant Claims
- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-072764 (JP '764, cited in the Office action mailed on 8/30/07).

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Applicant Claims

Applicant claims a cosmetic material comprising a crosslinked product of a poly- γ -glutamic acid and/or a crosslinked product of a poly- γ -glutamic acid salt having a particle size of 0.1 to 100 μ m and an average particle size of 1 to 50 μ m.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

JP '764 is directed to substrates for cosmetics. A cross-linked polyamino acid is used for the base material. The crosslinked polyamino acid preferably has a backbone comprising a homopolymer of polyaspartic acid, polyalutamic acid, or polylysine (abstract, solution). It is additionally disclosed that the polyamino acid can be in the form of an alkaline metal salt, ammonium salt or amine salt (paragraph 37). It is disclosed that the particle size of the poly amino acid will differ according to usage and the purpose of use. When it is used as cosmetics, in order to obtain a slide nature, stretch, and a not rough feeling a size of the polyamino acid utilized is from 10 nm to 500 micrometers, preferred 100 nm to 200 micrometers and more preferred are from 1 micrometer to 100 micrometers (paragraph 0041). Exemplified are particle sizes of 100 micrometers or less (paragraph 0062). The amount of the polyamino acid is from 0.001 to 50% of the weight (paragraph 0050). Additive agents include those typical used for skin cosmetics for example surfactants, oils, coat forming agent, etc. (paragraph 0051). It is disclosed the invention can be used for skin cosmetics as well as hair cosmetics (paragraphs 0051 and 0052). It is disclosed in Example 4 (paragraph 0066) that the cosmetic cream containing polyaspartic acid in 0.5%, liquid paraffins in 25% as well as

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other common ingredients created a cleansing cream that left a refreshed and smooth effect on the skin.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

JP '764 does not exemplify utilizing polyglutamic acid. However, JP '764 does indicate that polyglutamic acid is suitable.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to substitute polyglutamic acid for polyaspartic acid in the invention of JP '764. One of ordinary skill in the art would have been motivated to utilize polyglutamic acid because it is disclosed in JP '764 as being a suitable polyamino acid to utilize in the invention. Furthermore, polyglutamic acid is a homolog of polyaspartic acid and one of ordinary skill in the would have had a reasonable expectation of success as similar structures are expected to have similar properties.

An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties. *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). **MPEP 2144.09**.

Regarding the claimed particle size, while JP '764 does disclose a broad range JP '764 indicates that smaller particle sizes are preferred and exemplifies utilizing less than 100 micrometer particle size. Furthermore, JP '764 indicates that in order to obtain a slide nature, stretch, and a not rough feeling these sizes are utilized. Therefore, one

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of ordinary skill in the art would have been motivated to utilize particle sizes of 100 micrometers or less as JP '764 indicates that these sizes are preferred so as to provide a beneficial effect on the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima* facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3-4 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001-072764 in view of JP 2001-354542 (JP '542, cited in the Office action mailed on 8/30/07).

Applicant Claims

Applicant claims that the crosslinked product of poly- γ -glutamic acid or salt thereof is produced by exposing at lease one solution to radiation for crosslinking.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of JP '764 are set forth above. Specifically JP '764 discloses utilizing crosslinked polyamino acids with exemplified particle size of 100 micrometers or less in cosmetics.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

JP '764 does not specify that the crosslinking occurs through radiation. However, this deficiency is cured by JP '542.

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JP '542 teach forming poly-γ-glutamic acid via radiation. The poly-γ-glutamic acid is dissolved in solvents such as water (paragraph 009) or methanol or ethanol (paragraph 0014) and irritated with radiation to produce a crosslinked poly-γ-glutamic acid (paragraphs 8 and 9). This method is inexpensive and affords a crosslinked poly-γ-glutamic acid with greater moisturizing effect (abstract and paragraph 007).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of JP '764 and JP '542 and utilize crosslinked poly- γ -glutamic acid formed via radiation. One of ordinary skill in the art would have been motivated to produce crosslinked poly- γ -glutamic acid in this manner as it is taught as a more inexpensive procedure as well as providing cross linked poly- γ -glutamic acid with a greater moisturizing effect, which would be beneficial for a cosmetic composition.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima* facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Amendment

The declaration under 37 CFR 1.132 filed March 20 2008 is insufficient to overcome the rejection of claims 1-6 and 8-11 based upon JP '764 as set forth in the

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last Office action because: the results are not unexpected and it is not a true showing of a side by side comparison.

Firstly the results are not unexpected. JP '764 exemplifies utilizing particle sizes of 100 micrometers or less, the same as instant claimed. JP '764 teach that the particle size would be adjusted in order to obtain a slide nature, stretch, and a not rough feeling. Applicant's declaration showing unexpected results evaluates the different particle size products based on moist feeling, tidy feeling, and neat feeling. While the results indicate that particle sizes above the claimed range results in a product that did not have a neat feeling, this is not surprising. The larger the particle size the grittier the composition would be. Therefore compositions with a larger particle size would not be expected to be neat. Applicant indicates in their response filed on March 20 2008 that comparative example 3 has an average particle size of 0.5 micrometers. However, #7 of the declaration and comparative example 3 in the specification indicate that the particle size is 0.1 micrometers which is the lower limit of the instantly claimed particle size. This particle size was indicated as not exhibiting a moist feeling.

Secondly, the results are not true comparison. JP '764 exemplifies polyaspartic acid. It would have been obvious to one of ordinary skill in the art to substitute polyglutamic acid for polyaspartic acid based on the teachings of JP '764. To demonstrate unexpected results, i.e. the substitution of polyaspartic acid for polyglutamic acid, the declaration would have to show a side by side comparison of polyglutamic acid and polyaspartic acid.

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Therefore, the declaration filed March 20 2008 is insufficient to overcome the rejection of record.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher Examiner Art Unit 1616 Art Unit: 1616

ΑF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616